SAFETY DATA SHEET

INVEGA

Version	Revision Date:	SDS Number:	Date of last issue: 2022/09/30
4.0	2022/11/08	100000014585	Date of first issue: 2018/04/13

SECTION 1. IDENTIFICATION

Product name : INVEGA
Substance name : INVEGA Extended-Release tablet, 6 mg paliperidone

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
Pharmacotherapeutic group: Psycholeptics
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.
P330 Rinse mouth.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidently leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
Polyethylene oxide	25322-68-3	>= 50 - < 70
PALIPERIDONE	144598-75-4	>= 5 - < 10
TITANDIOXIDE	13463-67-7	>= 1 - < 5
Octadecanoic acid	57-11-4	>= 0.1 - < 1
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	< 0.1
Polyethylene oxide	25322-68-3	>= 50 - < 70
PALIPERIDONE	144598-75-4	>= 5 - < 10
TITANDIOXIDE	13463-67-7	>= 1 - < 5
Octadecanoic acid	57-11-4	>= 0.1 - < 1
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled	:	Health injuries are not known or expected under normal use. If breathed in, move person into fresh air. Consult a physician.
In case of skin contact	:	Take off contaminated clothing and shoes immediately. Wash off with soap and water. If symptoms persist, call a physician.
In case of eye contact	:	Remove contact lenses. Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. If eye irritation persists, consult a specialist.
If swallowed	:	If swallowed, rinse mouth with water (only if the person is conscious). Call a physician immediately.
Most important symptoms and effects, both acute and delayed	:	Consult the patient packaging insert for more information about this Finished Pharmaceutical Product. constipation Dizziness Drowsiness headache indigestion insomnia nausea Spasm tachycardia Tremors restlessness calming psychotic disorders weight increase
Notes to physician	:	Treat symptomatically. Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Hazardous combustion products	:	No hazardous combustion products are known
Further information	:	No information available.
Special protective equipment	:	In the event of fire, wear self-contained breathing apparatus.

for firefighters

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Environmental precautions	:	Should not be released into the environment.
Methods and materials for containment and cleaning up	:	Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations". Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal.Pick up and arrange without creating dust. Keep in properly labelled containers. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	No data available
Advice on safe handling	:	To avoid thermal decomposition, do not overheat. Avoid inhalation, ingestion and contact with skin and eyes. Do not break, crush or spill this Finished Pharmaceutical Product. Use personal protective equipment as required.
Conditions for safe storage	:	Keep away from heat and sources of ignition. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep locked up. Store in original container. To maintain product quality, do not store in heat or direct sunlight.
Recommended storage temperature	:	59 - 77 °F / 15 - 25 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyethylene oxide	25322-68-3	TWA	10 mg/m3	US WEEL

		(aerosol)		
PALIPERIDONE	144598-75-4	TWA	0.006 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 A	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3A.			
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m3 (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH
Octadecanoic acid	57-11-4	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m3	ACGIH
		TWA	10 mg/m3	ACGIH
		TWA	10 mg/m3	NIOSH REL
		TWA	10 mg/m3	OSHA P0
Polyethylene oxide	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL
PALIPERIDONE	144598-75-4	TWA	0.006 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 A	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3A.			

TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m3 (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH
Octadecanoic acid	57-11-4	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m3	ACGIH
		TWA	10 mg/m3	ACGIH
		TWA	10 mg/m3	NIOSH REL
		TWA	10 mg/m3	OSHA P0

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Maxxam Analytics (www.maxxamlabs.com) or the Laboratory of Occupational and Environmental Hygiene (www.lamh.be).

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Remarks : Disposable gloves

Eye protection	:	No special precautions required.
Skin and body protection	:	closed work clothing
Protective measures	:	The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet
Colour	:	No data available
Odour	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable

Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	Heat, flames and sparks. Exposure to moisture To avoid thermal decomposition, do not overheat.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate: 753.67 mg/kg Method: Calculation method

Components:

Polyethylene oxide:

Acute oral toxicity	:	LD50 (Rat): 4,000 mg/kg Assessment: The component/mixture is minimally toxic after single ingestion. Remarks: Information given is based on data obtained from similar substances.
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	Remarks: No data available

PALIPERIDONE:

Acute oral toxicity	:	LD50 (Rat, female): 56.6 mg/kg

LD50 (Rat, female): 65 mg/kg

LD50 (Rat, male): 112 mg/kg

LD50 (Rat, female): 149 mg/kg

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Rabbit): > 2,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Polyethylene oxide:

Acute oral toxicity : LD50 (Rat): 4,000 mg/kg
Assessment: The component/mixture is minimally toxic after single ingestion.
Remarks: Information given is based on data obtained from similar substances.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

PALIPERIDONE:

Acute oral toxicity : LD50 (Rat, female): 56.6 mg/kg

LD50 (Rat, female): 65 mg/kg

LD50 (Rat, male): 112 mg/kg

LD50 (Rat, female): 149 mg/kg

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Rabbit): > 2,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Components:

Polyethylene oxide:

Species	:	Rabbit
Exposure time	:	4 h
Result	:	No skin irritation
Remarks	:	Information given is based on data obtained from similar substances.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Result	:	Mild skin irritation

Polyethylene oxide:

Species	:	Rabbit
Exposure time	:	4 h
Result	:	No skin irritation
Remarks	:	Information given is based on data obtained from similar substances.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Result	:	Mild skin irritation

Serious eye damage/eye irritation

Components:

Polyethylene oxide:

Species	:	Rabbit
Result	:	No eye irritation
Remarks	:	Information given is based on data obtained from similar substances.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Remarks	:	No data available

Polyethylene oxide:

Species	:	Rabbit
Result	:	No eye irritation
Remarks	:	Information given is based on data obtained from similar substances.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Remarks	:	No data available

Respiratory or skin sensitisation

Components:

Polyethylene oxide:

Remarks : No data available

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Remarks : No data available

Polyethylene oxide:

Remarks : No data available

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Remarks : No data available

Germ cell mutagenicity

Components:

Polyethylene oxide:

Genotoxicity in vitro : Remarks: No data available

PALIPERIDONE:

Genotoxicity in vitro : Test Type: Ames test
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative

Test Type: A mouse lymphoma test
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Result: negative

Germ cell mutagenicity - Assessment : Animal testing did not show any mutagenic effects.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Germ cell mutagenicity - Assessment : No information available.

Polyethylene oxide:

Genotoxicity in vitro : Remarks: No data available

PALIPERIDONE:

Genotoxicity in vitro : Test Type: Ames test
Method: Mutagenicity (Salmonella typhimurium - reverse

mutation assay)
Result: negative

Test Type: A mouse lymphoma test
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Result: negative

Germ cell mutagenicity - Assessment : Animal testing did not show any mutagenic effects.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Germ cell mutagenicity - Assessment : No information available.

Carcinogenicity

Components:

Polyethylene oxide:

Species : Rat
Application Route : Oral
Exposure time : 2 years
Dose : 1000 - 1300 mg/kg/day
Remarks : Did not show carcinogenic effects in animal experiments.

PALIPERIDONE:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Carcinogenicity - Assessment : No information available.

Polyethylene oxide:

Species : Rat
Application Route : Oral
Exposure time : 2 years
Dose : 1000 - 1300 mg/kg/day
Remarks : Did not show carcinogenic effects in animal experiments.

PALIPERIDONE:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Carcinogenicity - : No information available.

Assessment

IARC Group 2B: Possibly carcinogenic to humans
13463-67-7 TITANDIOXIDE

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Components:

Polyethylene oxide:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

PALIPERIDONE:

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Teratogenicity - Assessment : Ingestion of excessive amounts by pregnant animals resulted in maternal and foetal toxicity.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Teratogenicity - Assessment : No information available.

Polyethylene oxide:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

PALIPERIDONE:

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Teratogenicity - Assessment : Ingestion of excessive amounts by pregnant animals resulted in maternal and foetal toxicity.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Teratogenicity - Assessment : No information available.

STOT - single exposure

Components:

Polyethylene oxide:

Remarks : No data available

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Remarks : No data available

Polyethylene oxide:

Remarks : No data available

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Remarks : No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

Polyethylene oxide:

Species : Rat
Application Route : Oral
Exposure time : 14 days
Dose : 50000 ppm
Symptoms : Gastrointestinal disturbance

Species : Rat
Application Route : Oral
Exposure time : 14 days
Dose : 20000 ppm
Remarks : No adverse effect has been observed in chronic toxicity tests.

Polyethylene oxide:

Species : Rat
Application Route : Oral
Exposure time : 14 days
Dose : 50000 ppm
Symptoms : Gastrointestinal disturbance

Species : Rat
Application Route : Oral
Exposure time : 14 days
Dose : 20000 ppm

Remarks : No adverse effect has been observed in chronic toxicity tests.

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Polyethylene oxide:

Toxicity to fish : LC50 (Cyprinodon sp. (minnow)): > 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 7,550 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : Remarks: No data available

PALIPERIDONE:

Toxicity to fish : NOEC (Danio rerio (zebra fish)): 2.5 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Danio rerio (zebra fish)): 18 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 23 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 2.1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants	:	EbC50 (Scenedesmus capricornutum (fresh water algae)): 14 mg/l Exposure time: 72 h Test Type: Cell multiplication inhibition test Method: OECD Test Guideline 201 ErC50 (Scenedesmus capricornutum (fresh water algae)): > 16 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201 NOECb (Scenedesmus capricornutum (fresh water algae)): 7 mg/l Exposure time: 72 h Test Type: Cell multiplication inhibition test Method: OECD Test Guideline 201 NOECr (Scenedesmus capricornutum (fresh water algae)): 7 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 3.2 mg/l Exposure time: 35 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 2.5 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	NOEC (activated sludge): >= 2,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 EC50 (activated sludge): > 2,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Toxicity to fish	:	(Fish): 0.199 mg/l Exposure time: 96 h Test Type: LC50
Toxicity to algae/aquatic plants	:	EC50: 0.758 mg/l Exposure time: 96 h
M-Factor (Acute aquatic toxicity)	:	1
M-Factor (Chronic aquatic	:	1

toxicity)

Polyethylene oxide:

Toxicity to fish	:	LC50 (Cyprinodon sp. (minnow)): > 10,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Daphnia magna (Water flea)): 7,550 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	Remarks: No data available

PALIPERIDONE:

Toxicity to fish	:	NOEC (Danio rerio (zebra fish)): 2.5 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 LC50 (Danio rerio (zebra fish)): 18 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 23 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 NOEC (Daphnia magna (Water flea)): 2.1 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EbC50 (Scenedesmus capricornutum (fresh water algae)): 14 mg/l Exposure time: 72 h Test Type: Cell multiplication inhibition test Method: OECD Test Guideline 201 ErC50 (Scenedesmus capricornutum (fresh water algae)): > 16 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201 NOECb (Scenedesmus capricornutum (fresh water algae)): 7 mg/l Exposure time: 72 h Test Type: Cell multiplication inhibition test Method: OECD Test Guideline 201 NOECr (Scenedesmus capricornutum (fresh water algae)): 7 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 3.2 mg/l Exposure time: 35 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 2.5 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	NOEC (activated sludge): >= 2,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 EC50 (activated sludge): > 2,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Toxicity to fish	:	(Fish): 0.199 mg/l Exposure time: 96 h Test Type: LC50
Toxicity to algae/aquatic plants	:	EC50: 0.758 mg/l Exposure time: 96 h
M-Factor (Acute aquatic toxicity)	:	1
M-Factor (Chronic aquatic toxicity)	:	1

Persistence and degradability

Components:

Polyethylene oxide:

Biodegradability	:	Remarks: No data available

PALIPERIDONE:

Biodegradability	:	Inoculum: activated sludge Result: Not readily biodegradable. Method: OECD Test Guideline 301F

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Biodegradability	:	Remarks: No data available

Polyethylene oxide:

Biodegradability	:	Remarks: No data available

PALIPERIDONE:

Biodegradability : Inoculum: activated sludge
Result: Not readily biodegradable.
Method: OECD Test Guideline 301F

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

Polyethylene oxide:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

PALIPERIDONE:

Partition coefficient: n-octanol/water : Remarks: No data available

TITANDIOXIDE:

Partition coefficient: n-octanol/water : Remarks: No data available

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Bioaccumulation : Bioconcentration factor (BCF): 598.4

Polyethylene oxide:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

PALIPERIDONE:

Partition coefficient: n-octanol/water : Remarks: No data available

TITANDIOXIDE:

Partition coefficient: n-octanol/water : Remarks: No data available

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Bioaccumulation : Bioconcentration factor (BCF): 598.4

Mobility in soil

Components:

PALIPERIDONE:

Distribution among environmental compartments : Adsorption/Soil
Medium: Soil
Koc: 9607
Method: OECD Test Guideline 106

Adsorption/Soil
Medium: Soil
Koc: 101602
Method: OECD Test Guideline 106

Adsorption/Soil
Medium: Soil
Koc: 53877
Method: OECD Test Guideline 106

Adsorption/Soil
Medium: Soil
Koc: 24008
Method: OECD Test Guideline 106

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Mobility : Remarks: No data available

PALIPERIDONE:

Distribution among environmental compartments : Adsorption/Soil
Medium: Soil
Koc: 9607
Method: OECD Test Guideline 106

Adsorption/Soil
Medium: Soil
Koc: 101602
Method: OECD Test Guideline 106

Adsorption/Soil
Medium: Soil
Koc: 53877
Method: OECD Test Guideline 106

Adsorption/Soil
Medium: Soil
Koc: 24008
Method: OECD Test Guideline 106

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Mobility : Remarks: No data available

Other adverse effects

Components:

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Environmental fate and pathways	:	No data available
Results of PBT and vPvB assessment	:	No information available.

Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-:

Environmental fate and pathways	:	No data available
Results of PBT and vPvB assessment	:	No information available.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	In accordance with National, Federal, State and Local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

TITANDIOXIDE	13463-67-7

Massachusetts Right To Know

TITANDIOXIDE	13463-67-7

Pennsylvania Right To Know

Polyethylene oxide	25322-68-3
sodium chloride	7647-14-5
PALIPERIDONE	144598-75-4
PVP K30 (KOLLIDON 30)	9003-39-8
TITANDIOXIDE	13463-67-7

Pennsylvania Right To Know

Polyethylene oxide	25322-68-3
sodium chloride	7647-14-5
PALIPERIDONE	144598-75-4
PVP K30 (KOLLIDON 30)	9003-39-8
TITANDIOXIDE	13463-67-7

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New Jersey Right To Know

Polyethylene oxide	25322-68-3
sodium chloride	7647-14-5
PALIPERIDONE	144598-75-4
PVP K30 (KOLLIDON 30)	9003-39-8
TITANDIOXIDE	13463-67-7

New York City Hazardous Substances

TITANDIOXIDE	13463-67-7
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0

New York City Hazardous Substances

TITANDIOXIDE	13463-67-7
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	128-37-0

California Prop. 65

WARNING! This product contains a chemical known to the State of California to cause cancer. WARNING: This product can expose you to chemicals including TITANDIOXIDE, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

PVP K30 (KOLLIDON 30)	9003-39-8

California List of Hazardous Substances

PVP K30 (KOLLIDON 30)	9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

TITANDIOXIDE	13463-67-7

California Permissible Exposure Limits for Chemical Contaminants

TITANDIOXIDE	13463-67-7

Other regulations

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	US. ACGIH Threshold Limit Values
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	Time weighted average
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response,

Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2022/11/08

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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